REMARKS

Applicants would like to express appreciation to the Examiner for the detailed Final Official Action provided.

Claims 1, 2, 5-13, 20-26, 35, and 36 are currently pending. Claims 1, 2, 7-13, and 20-26 have been withdrawn from consideration by the Examiner as being directed to a nonelected invention. Applicants respectfully request reconsideration of the outstanding rejections and allowance of claims 5, 6, 35, and 36 in the present application. Such action is respectfully requested and is now believed to be appropriate and proper.

The Examiner has rejected claims 5 and 35 under 35 U.S.C. § 103(a) as being unpatentable over PRUITT (US 6,458,076) in view of HIRATA (US 7,591,781).

However, Applicants respectfully submit that PRUITT and HIRATA fail to teach or suggest the subject matter claimed in claim 5. In particular, claim 5 sets forth an internal treatment apparatus having a flexible tubular body to be introduced into a patient including, inter alia, "a center opening for inserting therethrough an endoscope for observing a target site, said center opening extending through said flexible tubular body from a center of a distal end face of said flexible tubular body, said distal end face facing said target site, and a plurality of circumferential holes through which surgical instruments are inserted for performing a surgical procedure on said target site, each of said plurality of circumferential holes being provided to extend through a side face of said flexible tubular body at said distal end of said flexible tubular body so that each of said plurality of circumferential holes is independent from said distal end face, and each of said plurality of circumferential holes is distinct from said center opening".

Applicants' claimed internal treatment apparatus and system is shown in Figures 7-14. The flexible tubular member has a distal end portion 111, and a center opening 220 that extends

through the flexible tubular member from the center of the distal end face 111b. The circumferential holes 131, 132 are open on the side surface of the flexible tubular body and extend through the flexible tubular body. As shown in figures 8 and 9, the circumferential holes 131, 132 are spaced from the distal end face 111b of the flexible tubular member, and are independent from the distal end face 111b of the flexible tubular member. Also as shown in figure 8, the center opening 220 is distinct from each of the circumferential holes.

As shown in figure 9, a stereoscopic endoscope 221 for observing the target site is inserted through the center opening 220 to protrude from the outlet 220b to the lesion. Further, surgical instruments 242 and 241 pass through the circumferential holes 131, 132. See page 27, line 14 through page 28, line 16.

The PRUITT patent discloses an endoscope 10 having a handle 12, a shaft 14, and a distal tip 16. The shaft 14 includes a central lumen 20 and auxiliary lumens 21-28. The central lumen 20 is a working channel for performing medical procedures such as surgery, drug delivery, or tissue sampling. Four of the auxiliary lumens receive pull wires therethrough for deflecting the tip 16, and the other auxiliary lumens receive light guides and image guides therethrough. The shaft 14, including the central lumen and the auxiliary lumens, is the endoscope 10 itself, as disclosed in the PRUITT patent. Therefore, the central opening of PRUITT does not receive an endoscope therein, as in Applicants' claimed invention. Accordingly, the PRUITT patent does not teach a central opening provided in an internal treatment apparatus.

The Examiner has taken the position that PRUITT discloses a center opening 20' capable of having an endoscope inserted therethrough and extending through the flexible tubular body. However, since the shaft 14, including the central lumen and the auxiliary lumen, is the

endoscope itself, the shaft with the central lumen therein cannot *also* receive the endoscope therein. In other words, the shaft 14 and central lumen cannot *both* be the endoscope itself and receive the endoscope therein. The central lumen is, as shown in figures 2 and 4, provided on the endoscope 10 itself, and consequently the central lumen could not be provided in an internal treatment apparatus. Accordingly, PRUITT fails to teach an internal treatment apparatus having a flexible tubular body including "a center opening for inserting therethrough an endoscope for observing a target site", as set forth in claim 5.

Further, as recognized by the Examiner, the PRUITT patent fails to teach or suggest a plurality of circumferential holes that extend through the side face of the flexible tubular body.

The HIRATA patent is directed to an endoscope with insertion direction changing guides. The Examiner has taken the position that HIRATA teaches a flexible internal treatment apparatus having a plurality of lumens 91a on the lateral sides of the distal end of the apparatus.

However, the HIRATA patent does not disclose or teach a flexible tubular body with a plurality of circumferential holes on the side face of the flexible tubular body as claimed. In this regard, the lumen 91a is formed on the guide member 10. See particularly figure 9A. The guide member is used to determine the forward moving direction of the endoscope 2 in the body cavity. As clearly shown in the figures, the guide member 10 does not have a center opening. In the operation of the HIRATA device, if the endoscope 2 can move straight ahead into the body cavity, or if there is no need to bend the endoscope 2 in the body cavity, the guide member 10 would be completely unnecessary. As disclosed in column 3, lines 54-57, the tubular members 8a, 8b, 8c are flexible. However, the guide member 10 (the guide tube 124) is provided for allowing the endoscope 2 to pass therethrough toward a desired direction. Although HIRATA shows a plurality of lumens, HIRATA does not disclose or teach a structure in which the

endoscope passes in one lumen and, simultaneously, a surgical instrument passes through another lumen, as in the present invention. Therefore, the guide member 10 of HIRATA is not equivalent to an internal treatment apparatus, as claimed.

Thus, contrary to the Examiner's assertions, HIRATA fails to teach or suggest lateral circumferential holes in a side face of a flexible tubular body having a center opening.

Therefore, the HIRATA patent fails to cure the deficiencies of the PRUITT device, and even assuming, arguendo, that the teachings of PRUITT and HIRATA have been properly combined, Applicants' claimed internal treatment apparatus would not have resulted from the combined teachings thereof.

Further, there is nothing in the cited prior art that would lead one of ordinary skill in the art to make the modification suggested by the Examiner in the rejection of claim 5 under 35 U.S.C. § 103(a) over PRUITT in view of HIRATA. Thus, the only reason to combine the teachings of PRUITT and HIRATA results from a review of Applicants' disclosure and the application of impermissible hindsight. Accordingly, the rejection of claim 5 under 35 U.S.C. § 103(a) over PRUITT in view of HIRATA is improper for all the above reasons and withdrawal thereof is respectfully requested.

Applicants submit that dependent claim 35, which is at least patentable due to its dependency from claim 5, for the reasons noted above, recites additional features of the invention and is also separately patentable over the prior art of record based on the additionally recited features. Accordingly, claim 35 is separately patentable for these additional reasons.

The Examiner has rejected claims 6 and 36 under 35 U.S.C. § 103(a) as being unpatentable over PRUITT (US 6,458,076) in view of HIRATA (US 7,591,781) and HARKRIDER (US 6,328,730).

However, Applicants respectfully submit that PRUITT, HIRATA, and HARKRIDER fail to teach or suggest the subject matter claimed in claim 6. In particular, claim 6 sets forth an internal treatment system including, inter alia, "a flexible tubular body to be introduced into a patient, said flexible tubular body including a center opening for inserting therethrough an endoscope for observing a target site, said center opening being circular in cross section and extending through said flexible tubular body from a center of a distal end face of said flexible tubular body, said distal end face facing said target site, and a plurality of circumferential holes through which surgical instruments are inserted for performing a surgical procedure on said target site, each of said plurality of circumferential holes being provided to extend through a side face of said flexible tubular body at said distal end of said flexible tubular body, so that each of said plurality of circumferential holes is independent from said distal end face, and each of said plurality of circumferential holes is distinct from said center opening; a body manipulating device for manipulating said flexible tubular body from outside said patient; an endoscope manipulating device for manipulating said endoscope from outside said patient; and a surgical instrument manipulating device for manipulating said surgical instruments from outside said patient".

As described above, Applicants' claimed internal treatment system includes the flexible tubular member having a distal end portion 111, and a center opening 220 that extends through the flexible tubular member from the center of the distal end face 111b. The circumferential holes 131, 132 are open on the side surface of the flexible tubular body and extend through the flexible tubular body.

Further, as shown in figure 9, the stereoscopic endoscope 221 is inserted through the center opening 220 to protrude from the outlet 220b to the lesion. Further, surgical instruments

242 and 241 pass through the circumferential holes 131, 132. See page 27, line 14 through page 28, line 16.

The PRUITT patent discloses an endoscope 10 having a handle 12, a shaft 14, and a distal tip 16. The shaft 14 includes a central lumen 20 for performing medical procedures such as surgery, drug delivery, or tissue sampling, and auxiliary lumens 21-28 that receive pull wires or light guides and image guides. The shaft 14, including the central lumen and the auxiliary lumens, *is* the endoscope 10, as disclosed in the PRUITT patent. Therefore, the central lumen cannot receive an endoscope therein, as in Applicants' claimed invention.

The Examiner has taken the position that PRUITT discloses a center opening 20' capable of having an endoscope inserted therethrough and extending through the flexible tubular body. However, since the shaft 14, including the central lumen and the auxiliary lumen, is the endoscope itself, the shaft with the central lumen therein cannot also receive the endoscope therein. In other words, the shaft 14 and central lumen cannot *both* be the endoscope and receive the endoscope therein. The central lumen is, as shown in figures 2 and 4, provided on the endoscope 10 itself, and consequently the central lumen is not provided on the internal treatment apparatus. Accordingly, PRUITT fails to teach an internal treatment apparatus having a flexible tubular body including "a center opening for inserting therethrough an endoscope for observing a target site", as set forth in claim 6.

Further, as recognized by the Examiner, the PRUITT patent fails to teach or suggest a plurality of circumferential holes that extend through the side face of the flexible tubular body, and an endoscope manipulating device for manipulating an endoscope inserted in the center opening and a surgical instrument manipulating device for manipulating surgical instruments inserted into the circumferential holes.

The Examiner has taken the position that HIRATA teaches a flexible internal treatment apparatus having a plurality of lumens 91a on the lateral sides of the distal end of the apparatus.

However, the HIRATA patent does not disclose or teach a flexible tubular body with a plurality of circumferential holes on the side face of the flexible tubular body as claimed. In this regard, the lumens 91a are provided on the guide member 10. The guide member 10 does not have a center opening. If the endoscope 2 can move forward straight ahead into the body cavity, or if the endoscope 2 need not bend in the body cavity, the guide member 10 would be unnecessary. The tubular members 8a, 8b, 8c are flexible, but the guide member 10 allows the endoscope 2 to pass therethrough toward a desired direction. Although a plurality of lumens are disclosed in the HIRATA device, HIRATA does not teach a device in which the endoscope passes in one lumen, and simultaneously a surgical instrument passes in another lumen. Therefore, the guide member 10 of HIRATA is not equivalent to the claimed internal treatment system.

Thus, contrary to the Examiner's assertions, HIRATA fails to teach or suggest circumferential holes in a side face of a flexible tubular body having a center opening.

Further, the Examiner has taken the position that HARKRIDER teaches an internal treatment apparatus with multiple lumens for inserting viewing instruments.

As an initial matter, is it noted that U.S. Patent No. 6,328,730 to HARKRIDER has not been made of record in the present application. Accordingly, it is respectfully requested that the Examiner cite the HARKRIDER patent to make the same formally of record in the present application.

Further, the HARKRIDER patent fails to teach or suggest a body manipulating device, an endoscope manipulating device, and a surgical instrument manipulating device as claimed. In

particular, the HARKRIDER patent is directed to an elongated, generally tubular, multi-lumen surgical catheter. Clearly, it would not be possible to form a hole through which an endoscope passes in the HARKRIDER device. Thus, it is respectfully submitted that the HARKRIDER patent is not relevant to the claimed internal treatment system.

Thus, contrary to the Examiner's assertions, HARKRIDER fails to teach or suggest a body manipulating device, an endoscope manipulating device, and a surgical instrument manipulating device as claimed.

Therefore, the HIRATA and HARKRIDER patents fail to cure the deficiencies of the PRUITT device, and even assuming, arguendo, that the teachings of PRUITT, HIRATA, and HARKRIDER have been properly combined, Applicants' claimed internal treatment apparatus would not have resulted from the combined teachings thereof.

Further, there is nothing in the cited prior art that would lead one of ordinary skill in the art to make the modification suggested by the Examiner in the rejection of claim 6 under 35 U.S.C. § 103(a) over PRUITT in view of HIRATA and HARKRIDER. Thus, the only reason to combine the teachings of PRUITT, HIRATA, and HARKRIDER results from a review of Applicants' disclosure and the application of impermissible hindsight. Accordingly, the rejection of claim 6 under 35 U.S.C. § 103(a) over PRUITT in view of HIRATA and HARKRIDER is improper for all the above reasons and withdrawal thereof is respectfully requested.

Applicants submit that dependent claim 36, which is at least patentable due to its dependency from claim 6, for the reasons noted above, recites additional features of the invention and is also separately patentable over the prior art of record based on the additionally recited features. Accordingly, claim 36 is separately patentable for these additional reasons.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections, and an early indication of the allowance of claims 5, 6, 35, and 36.

SUMMARY AND CONCLUSION

In view of the foregoing, it is submitted that the present response is proper and that none of the references of record, considered alone or in any proper combination thereof, anticipate or render obvious Applicants' invention as recited in claims 5, 6, 35 and 36. The applied references of record have been discussed and distinguished, while significant claimed features of the present invention have been pointed out.

Accordingly, consideration of the present response, reconsideration of the outstanding Official Action, and allowance of all of the claims in the present application are respectfully requested and now believed to be appropriate.

Applicants have made a sincere effort to place the present application in condition for allowance and believe that they have now done so.

Should there be any questions, the Examiner is invited to contact the undersigned at the below listed number.

Respectfully Submitted,
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